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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,162	07/31/2001	Jean-Christophe Renauld	LUD 5684.2 CIP (10106926)	3161

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,162	RENAULD ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,17,18 and 31-33* is/are pending in the application.

4a) Of the above claim(s) *33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,17,18,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12,17,18 and 31-33* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/10/01 & 9/9/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's election with traverse of Group I invention, claims 1-12, 17 and 18, directed to SEQ ID NO:10, filed on 29 July 2004 is acknowledged. The traversal is on the ground(s) that SEQ ID NO:5 is a splice variant of SEQ ID NO:10, that the two sequences differ from one another by only 96 nucleotides, and conducting a search of the two sequences would not constitute an undue search burden on the examiner because any search of either SEQ ID NO:5 or 10 would locate the other. This is not found persuasive because even though SEQ ID NO:5 and 10 are related, and a sequence search of SEQ ID NO:5 may or may not reveal the result anticipating SEQ ID NO:10, as they comprise different sequence structure. Further, it is difficult to identify the sequence related to SEQ ID NO:10 from the search result of SEQ ID NO:5. As such, separate searches are required for SEQ ID NO:5 and 10, which constitute undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's amendment filed on 29 July 2004 is acknowledged and entered. Following the amendment, claims 13-16 and 19-30 are canceled, and the new claims 31-33 are added.

Currently, claims 1-12, 17, 18 and 31-33 are pending, and claims 1-12, 17, 18, 31 and 32 are under consideration. Claim 33 is withdrawn from further consideration as being drawn to a non-elected invention.

Formal Matters:

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 6, lines 9, 10 and 19, for example). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claims 1 and 4-12 are objected to for the following informalities, appropriate correction is required for each item:

Claim 1, line 2, the word "compliment" should be "complement".

Claims 4-12 are objected to for missing an article. "An expression vector" or "a recombinant cell" is suggested.

Double Patenting Rejections:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-12 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 of copending Application No. 10/385,586. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 17, 18, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is incomplete for omitting essential elements. The claim is limited by a hybridization method under stringency conditions. However, the claims recite neither hybridization conditions to ensure that any hybridized polynucleotides will comprise specific sequence within the meaning of the disclosure, nor process steps, which would effect the removal of nonspecific hybridization complexes. Examples of "stringent conditions" are noted in the specification (page 13, line 23 to page 14, line 3). However, examples of such fall within the intended definition, and are not considered, in themselves, to provide definitive conditions for the hybridization. As the target sequence is specific, an artisan needs to know the specific corresponding hybridization conditions in order to practice the claimed invention. Without such, one cannot determine the metes and bounds of nucleic acids within the limitations of the claim.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and the dependent claims 4, 7, 10, 17, 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an isolated nucleic acid having a nucleotide sequence of SEQ ID NO:5, or encoding a polypeptide of SEQ ID NO:6, and a variant at least 90% identical to SEQ ID NO:5 and encoding a functional polypeptide, does not reasonably provide enablement for claims to an isolated nucleic acid which complimentary sequence hybridizes to SEQ ID NO:5 under stringent conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claim 1 is directed to a nucleic acid, which complementary sequence hybridizes to SEQ ID NO:5 under stringent conditions. It is well known in the art that hybridization will occur even under stringent conditions if there is only local identity between two molecules whose sequences might be totally divergent outside of that region. Such hybridized molecules may encode proteins sharing partial sequence homology to SEQ ID NO:6 and binding to IL-TIF/IL-22, yet distinct in overall sequence structure and in other biological properties from that of the SEQ ID NO:6. The specification does not clearly define a specific hybridization condition for obtaining the claimed species, or working examples of any such variants, which would be within the limitations of the claims. Further, the specification provides no structure and functional relationship of the polypeptide. Therefore, it would require undue experimentation in order to make the claimed invention in a manner commensurate with its full scope.

Due to the large quantity of experimentation necessary to determine how to make the invention commensurate in scope with the claims, the lack of clear direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing that hybridization would occur between molecules sharing only local degree of sequence homology, and the breadth of the claims which embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make the claimed invention in its full scope.

Claim 1 and the dependent claims 4, 7, 10, 17, 18 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The specification discloses one nucleic acid, SEQ ID NO:5, which encodes a polypeptide of SEQ ID NO:6, and no other variants meeting the limitations of the claims were ever identified or particularly described. With the exception of SEQ ID NO:5 and those encoding SEQ ID NO:6, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, nor would be able to reasonably expect, for example, the requirement that a molecule hybridizing to said polynucleotide would correlate with the translation of a protein and retention of biological property of binding to IL-TIF/IL-22. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid of SEQ ID NO:5 or those encoding the amino acid sequence of SEQ ID NO:6, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a specified activity, such as induction of TNF- or IL-6. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 7, 8, 10, 11, 17, 18, and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Presnell et al., US2002/0012669 A1.

Presnell discloses a nucleic acid, SEQ ID NO:1, which sequence comprises nucleotides 22-776 of the present SEQ ID NO:5 with 100% identity, and encodes a soluble cytokine receptor, "Zcytor16" (SEQ ID NO:2), with an amino acid sequence 100% identical to the present SEQ ID NO:6 (see appended computer printout of sequence search results). With respect to the limitation of "a soluble protein which binds to IL-TIF/IL-22", as the amino acid sequence of the prior art is identical to that of the present invention, it would be the inherent property of Zcytor16 to bind to IL-TIF/IL-22. Therefore, Presnell's SEQ ID NO:1 anticipates claims 1, 2 and 31 as being a nucleic acid which complimentary sequence hybridizes to SEQ ID NO:5, or which encodes a protein having SEQ ID NO:6. Additionally, Presnell teaches an expression vector comprising the nucleic acid, a host cell thereof, and a recombinant method of producing the encoded protein (page 2, [0014], and page 5, [0049] and [0050]). As such, the reference also anticipates claims 4, 5, 7, 8, 10, 11, 17 and 18.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
9/16/04